



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 22-AUG-2017

Subject: Novaluron in/on Cotton, Pome Fruits, and Potato. **Response to Health Effects Division (HED) Review of 31-JAN-2008 (DP# 336897).**

PC Code: 124002

Decision No.: 531781

Petition No.: 2F06430

Risk Assessment Type: NA

TXR No.: NA

MRID No.: 47486301

DP Barcode: D441753


Registration No.: 66222-35

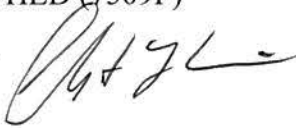
Regulatory Action: Sec. 3 Registration

Case No.: 7615

CAS No.: 116714-46-6

40 CFR: §180.598

From: George F. Kramer, Ph.D., Senior Chemist 
Risk Assessment Branch 1 (RAB1)/HED (7509P)

Through: Christine L. Olinger, Branch Chief 
RAB1/HED (7509P)

To: Margaret Hathaway, RMIB II
Pesticide Re-Evaluation Division (RD; 7505P)
and
Matthew Sellner, PM Team 10
Registration Division (RD; 7505P)

Executive Summary

Novaluron (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide) is a benzoylphenyl urea pesticide insect-growth regulator. Tolerances for residues of novaluron are established under 40 CFR §180.598 in/on a wide variety of crops. The Human Health Assessment Scoping Document was completed in 2015 (Memo, J. Van Alstine, *et al.*; 16-MAR-2015; D422124).

Data in support of this petition were originally reviewed by HED under D336897 (31-JAN-2008, S. Levy). The current amendment addresses the only remaining deficiency identified in this review and the only residue chemistry data deficiency identified in the Scoping Document.

Remaining Residue Chemistry Deficiencies

None

Regulatory Recommendations

HED concludes that there are no residue chemistry issues that would preclude granting unconditional registration for the use of novaluron on cotton, pome fruits, and potatoes. Additionally, the data reviewed in this amendment resolves the residue chemistry data deficiency identified in the Human Health Assessment Scoping Document (Memo, J. Van Alstine, *et al.*; 16-MAR-2015; D422124).

DETAILED CONSIDERATIONS**Deficiency - 860.1380 Storage Stability (from Memo, S. Levy, D336897; 31-JAN-2008)**

- The poultry feeding study will be classified as scientifically acceptable, pending submission of additional storage stability information. Sample storage intervals for poultry commodities were not reported, nor was it demonstrated that the storage interval for the residue samples was less than 1 month. Storage stability data for novaluron residues should be submitted that support the storage conditions and intervals of poultry egg and poultry skin/fat, muscle, liver, kidney, and abdominal fat tissue samples used in this study or the petitioner should demonstrate that the storage interval for the residue samples was less than one month.

Petitioner's Response: Makhteshim-Agan of North America has submitted:

MRID# 47488301 Supplemental Information on Novaluron: Residue Transfer Study, Sampling and Analysis Dates for Eggs and Tissues of Laying Hens. Supplement to: Rogers, M. (2006) Rimon: Residue Transfer Study - Accumulation and Depletion of Residues in Eggs and Tissues of Laying Hens. Project No.: MAK/0900/062531, prepared by Huntingdon Life Sciences, Ltd.; MCW Report No. R-18701.

All samples were analyzed within 14 days of collection.

HED's Conclusion: The requested data have been provided; this deficiency is now resolved. As the storage interval for the samples was less than one month, additional storage stability data are not required.